PCT/JP2003/008306

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference OP2003-026	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/JP2003/008306	International filing date (*day/month/year*) 30 June 2003 (30.06.2003)	Priority date (*day/month/year*) 01 July 2002 (01.07.2002)
International Patent Classification (IPC) or national classification and IPC C12N 15/00-90, C12N1/00-7/08, C07K 14/00-16/46, C12P 21/00-08		
Applicant OKADA, Hidechika		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:

      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

   ☒ Box No. I Basis of the report
   ☐ Box No. II Priority
   ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   ☐ Box No. IV Lack of unity of invention
   ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   ☐ Box No. VI Certain documents cited
   ☐ Box No. VII Certain defects in the international application
   ☒ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
09 January 2004 (09.01.2004)	20 May 2004 (20.05.2004)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:

☐ international search (under Rules 12.3 and 23.1(b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ The international application as originally filed/furnished

☐ the description:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

pages _____, as originally filed/furnished

pages* _____, as amended (together with any statement) under Article 19

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the drawings:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-6	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-6	NO
Industrial applicability (IA)	Claims	1-6	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Document 1: WO, 97-22361, A1 (Otsuka Pharm Co., Ltd.), 26 June, 1997 (26.06.97), & JP, 9-227409, A, & EP, 0870509, A1 & US, 6190863, B1
Document 2: Anti-HIV Activities of Human IgM Antibody to Carbohydrate Antigen GM2, (Noriko Okada, et al.), Journal of Nagoya City University Medical Society, 1999, Vol. 50, No. 1/2, pages 9-13
Document 3: The IgM Antibody Level against Ganglioside GM2 Correlates to the Disease Status of HIV-1-Infected Patients, (Wu Xiaoshan, et al.), Microbiology and Immunology, 2000, Vol. 44, No. 5, pages 405-410
Document 4: Human IgM Monoclonal Antibody to Ganglioside GM2 and Complement Suppress Virus Propagation in Ex Vivo Cultures of Lymphocytes from HIV-1 Infected Patients, (Noriko Okada, et al.), Microbiology and Immunology, 1999, Vol. 43, No. 7, pages 723-727

Claims 1-6

Documents 1-4 describe human IgM monoclonal antibodies to GM2, which is a carbohydrate recognition antigen, that lyse HIV-infected cells by activating complements. In view of the fact that monoclonal antibodies of the above claims are not different from the monoclonal antibodies of documents 1-4 in the function of lysing HIV-infected cells by activating complements, the subject matters of the above claims merely mean that alternatives to the monoclonal antibodies of documents 1-4 are acquired and their nucleic acid sequences are identified. A person skilled in the art could have easily achieved it. Accordingly, the subject matters of the above claims do not appear to involve an inventive step in view of documents 1-4.

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1-4

The monoclonal antibodies described in claims 1 and 2 are specified only in terms of the function, and those described in claims 3 and 4 are specified only by the nucleic acid sequence of the variable region of either H chain or L chain. The specification, however, only discloses as such monoclonal antibodies, e.g., human IgM monoclonal antibodies wherein the variable region of H chain has the nucleic acid sequence of SEQ ID NO: 1 and also the variable region of L chain has the nucleic acid sequence of SEQ ID NO: 2, or human IgM monoclonal antibodies that are produced by the cell line of Deposit No. FERM BP-8379. What other monoclonal antibodies are encompassed in the monoclonal antibodies of claims 1-4, in other words, what antigens such monoclonal antibodies bind to, or what structure they have, or by what cell lines they are produced, are unclear.

Accordingly, the subject matters of the above claims are not adequately supported by the specification, or are not disclosed sufficiently clearly and adequately that a person skilled in the art in the field could implement them.

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Supplemental Box Relating to Sequence Listing

Continuation of Box No. 1, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis that of:

   a. type of material

   ☒ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material

   ☐ in written format

   ☒ in computer readable form

   c. time of filing/furnishing

   ☐ contained in the international application as filed

   ☒ filed together with the international application in computer readable form

   ☐ furnished subsequently to this Authority for the purpose of search and/or examination

   ☐ received by this Authority as an amendment* on _____

2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

** If item 4 in Box No. I applies, the listing and /or table(s) related thereto, which form part of the basis of the report, may be marked "superseded".*